DISSERTATION

on

A STUDY OF EVALUATION OF THE EFFICACY OF EPIDURAL BUPIVACAINE WITH SUFENTANIL FOR LABOR ANALGESIA

M.D. DEGREE EXAMINATION

BRANCH -X

(ANAESTHESIOLOGY)

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CERTIFICATE

This is to certify that this Dissertation entitled, "A STUDY OF EVALUATION OF THE EFFICACY OF EPIDURAL BUPIVACAINE WITH SUFENTANIL FOR LABOR ANALGESIA" is the bonafide record of work done by **Dr.D. NIRANJAN**, submitted as partial fulfillment for the requirements of M.D. Degree Examinations Branch X,ANAESTHESIOLOGY, September 2006.

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CONTENTS

INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage[40]. Among these labor is a very painful process. It represent the most common form of acute severe pain in adult life, the severity compared to that of causalgia, cancer pain and amputation of digit and expressed as worst pain experienced by the patient.

Labor pain produces significant deleterious effect on mother and the fetus. It Increases the maternal mean arterial pressure due to stress induced release of catecholamines that cause concomitant decrease in uterine blood flow and subsequent fetal adverse effects[21, 22]. Pain induced hyperventilation shift O_2-Hb dissociation curve to the left. This causes increased affinity of hemoglobin for oxygen which makes unloading of O_2 to fetus unfavorable. After initial period of hyperventilation parturient may hypoventilate which may lead to decrease in arterial oxygen saturation[18]. This decrease in oxygenation may cause fetal acidosis. Labor pain increases incoordinate labor with irregular contractions.

Among the various methods of labor analgesia, epidural analgesia is the effective method to combat this unfavorable pain and it is widely practiced[24].

AIM OF THE STUDY

The aim of this study is to assess the efficacy of epidural bupivacaine with sufentanil for pain relief in labor and to assess the complications and neonatal outcome.

METHOD OF LABOR ANALGESIA

The early theory of obstetric analgesia was proposed by Grantly Dick-Read[5], called theory of natural child birth. He concluded that pain is due to fear-tension-pain syndrome. In this, fear incites tension in the circular muscle fibers of the lower part of the uterus. He advocated muscle relaxation exercises and breathing exercise to decrease the pain. The second major theory of child birth preparation was developed in Russia in 1954 by a Nikolayev, known as psycho prophylaxis. Dr. Fernand Lamaze[6], a French obstetrician modified this technique and popularized it in United States which is famously called as Lamaze technique. It is a modified version of the Dick-Read method. It comprises of three distinct components. First the pregnant mother was informed about the normal anatomy and physiology of pregnancy, labor and delivery. The second component is relaxation training for the mother. Third component consist of breathing techniques. In Lamaze's method husband takes an active role and provides support.

Later, another technique of pain relief, called acupuncture was developed in China[7]. This is based on the principle that energy flow patterns in the body are essential for normal health. Labor pain disrupts this energy flow. Scientific studies shows that acupuncture restore this disruption by releasing endogenous opioids.

OTHER METHODS:

Transcutaneous electrical nerve stimulation (TENS)[8,9]

It is based on gate control theory. According to this, cells in the posterior horn of the spinal gray matter have a gating function. Activity in low threshold, large afferent

fibers (not conducting pain) closes that gate to the pain path ways. Pain experienced is controlled by the balance between the activity in the low threshold, large afferent fibers which have no pain function, and that in the afferent pain fibers. The advantages of TENS are it is safe, non invasive, can be reversed at anytime and decreased need for narcotics. The major disadvantages are, less effectiveness and inadequate pain relief.

Systemic medications:[10]

Variety of drugs can be used for labor pain including Benzodiazepines, Barbituratus, Ketamine opioids and others. The advantages of systemic medications are they are simple to administer, do not require technically qualified persons to administer, can be given at any time during the labor and they can be given in the ward itself with sufficient monitoring. Also this type of analgesia can be used when regional anaesthesia is contraindicated. Systemic medications also has some disadvantages. They do not provide complete analgesia. They can cause sedation and respiratory depression in the mother and fetus. It also delays gastric emptying time leading to increased chance of aspiration.

Inhalational agents[11,12]

Inhalational analgesia is defined as administration of sub anesthetic concentrations of inhaled anesthetic to relieve labor pain. Various inhalational agents are being used for pain relief in labour including nitrous oxide, volatile agents and entonox. The major advantages are, they are easy to administer, rapidly equilibrate due to decreased FRC and increased minute ventilation in pregnant women. They can be eliminated rapidly

and can be easily titrated. The disadvantages are ineffective analgesia, depression of consciousness of the mother which may hinder her cooperation and abolish protective reflexes. They also produce adverse cardiovascular effects. Moreover they may cause uterine relaxation.

Paracervical block:[13,37]

It is a relatively simple method used to provide analgesia during labor. Local anesthetic is injected submucosally into the fornix of the vagina lateral to the cervix. It blocks all visceral sensory fibers from the uterus, cervix, and upper vagina. The disadvantages are it cannot be used for the second stage of labor. Moreover it produces fetal bradycardia, decreased oxygenation and fetal acidosis. Maternal complications like soft tissue injury and hematoma can also occur.

Lumbar sympathetic block:

Bilateral lumbar sympathetic block interrupts the pain impulses from the uterus, cervix, and upper third of vagina without motor blockade. It may be used to provide analgesia during the first stage of labor. It is useful in patients with previous surgery on the back which precludes administration of epidural. The disadvantages are maternal hypotension, retroperitoneal hemorrhage.

Combined spinal epidural analgesia:[36]

It produces rapid on set of analgesia and can be given at any stage of labor. It is associated with minimal hypotension. Decreases total dose requirement and preserve mobility. The disadvantages are fetal bradycardia and respiratory depression. It takes

comparatively longer time to administer this technique. Test dose cannot be given. It is not cost effective.

Continuous infusion epidural analgesia (CIEA)

Continuous Infusion Epidural Analgesia provides continuous and stable anesthetic level. Total local anesthetic requirement is less. Since lower concentrations of local anesthetic are used the tone of pelvic muscle is preserved thereby the motor blockade is minimal which decreases incidence of malrotation, instrumental deliveries and cesarean section, and also allows mothers to have greater mobility. Hypotensive episodes are less. The disadvantages are accidental over dosage hence it needs close monitoring. Epidural catheter may migrate to intravascular or subarachnoid space during the infusion.

Patient controlled epidural analgesia (PCEA)

Patient controlled epidural analgesia is a safe and effective technique, it gives excellent patient satisfaction. Local anesthetic requirement is less. Here also motor blockade is minimal and maternal hypotension is also less. The disadvantages are accidental over dosage and inadvertent migration of epidural catheter. Cost is comparatively high. .

HISTORY OF EPIDURAL ANALGESIA

In 1901- Sicard and Cathelin introduced caudal approach to epidural anesthesia . In 1921- Fidel pages described lumber epidural which is popularised by Dogliotti. In 1942- Hingson and Edwards introduced continues caudal. In 1949- Cleland described double catcher technique for labor analgesia one catheter in thoraco-lumbar region for stage I and another passed through sacral hiatus for stage II. In 1950's– many Anesthesiologists felt double catheter technique is cumbersome and adopted single lumbar catheter technique. Later it was found that high volume of local anesthetics by caudal epidural is associated with altered neonatal acid-base status and increased neonatal depression.

Contrary to the previous reports, then it was found that small doses of local anesthetics through lumbar epidural catheter would ensure adequate pain relief of first and second stages of labor and become preferred technique over caudal and is almost exclusively practiced today.

ANATOMY OF EPIDURAL SPACE

Epidural space is a potential space that extends from foramen magnum to sacral hiatus[43]. It actually lies in between two layers of duramater.In the cranium the 2 layers of dura i.e., the endosteal and meningeal layers are closely united .Below foramen magnum they separate and the outer one forms periosteal lining of the spinal canal and inner layer forms spinal dura,with epidural space lying in between.

Boundaries

Above **:**Foramen magnum where the periosteal and spinal layers fuse together

Below **:**Sacrococcygeal membrane

Anterior **:**The posterior longitudinal ligament covering the posterior aspect of vertebral bodies and intervertebral discs

Posterior **:**Anterior surface of vertebral lamina and ligamentum flavum.

Lateral **:**Pedicles of vertebra and intervertebral foramina

The contents of epidural space includes nerve roots that traverse it from foramina to peripheral locations, the Batson plexus of valve less veins, epidural fat and lymphatics. It is not an empty space hence various factors may affect the spread of

injected solutions.

The pressure inside the epidural space is negative relative to atmospheric pressure. In lower lumbar region it is about –0.5 cm H_2O to –1 cm H_2O. In the upper lumbar region it is about –1 to –3 cm H_2O. Pressure in the thoracic region is more negative compared to lumbar region. Pressure may become positive in pregnancy.

Anatomical changes in pregnancy

The enlarged gravid uterus compress inferior vena cava and increases the pressure. This forces blood to flow through the sacral venous plexus and the vertebral extra dural veins to superior vena cava. During each contraction uterus pumps about 300 to 500 ml of blood to augment flow through the vertebral extra dural venous plexus. Peaks of extra dural pressure rises about 8 to 10 cm of H_2O with each contraction. This anatomical change decreases epidural space volume and the injected solution spreads to a higher level compared to non pregnant women.

ANATOMY AND PHYSIOLOGY OF LABOR PAIN

Anatomy and physiology of labor pain

Pain perception by the parturient is a dynamic process that involves both peripheral and central mechanisms. Many factors contribute to pain in labor including psychological and emotional factors, past experiences, patient expectations of the birthing process and abnormal presentations. Mc Gill pain questionnaire depicts that labor pain is one of the most intense pain that a woman can experience

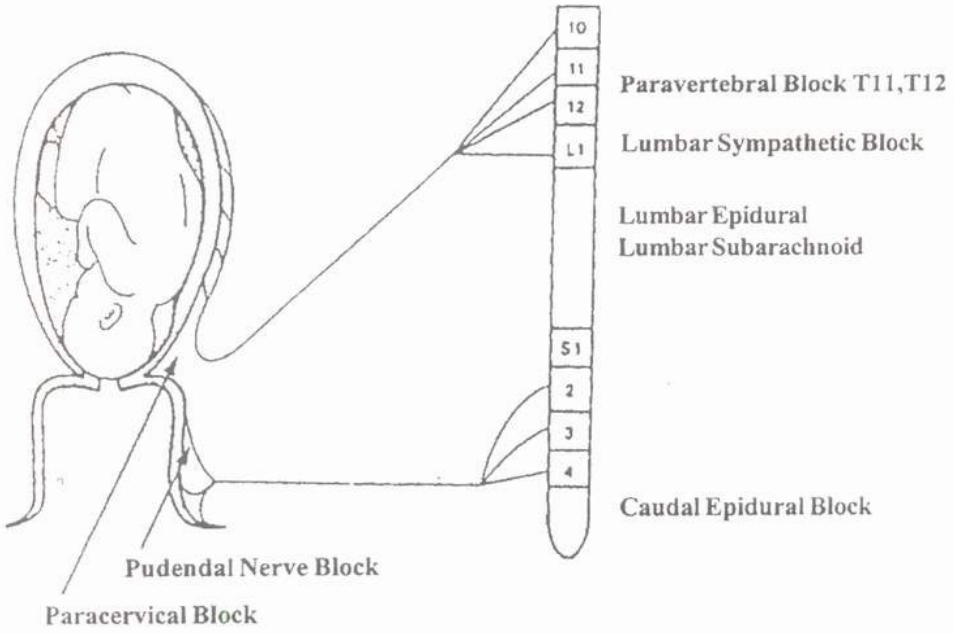
Primary hyperalgesia

It occurs at the site of injury due to sensitization of peripheral receptors of A delta and C fibres. Central sensitisation has little role.

Secondary hyperalgesia[2,3]

Occurs at a distance from the site of injury. Mediated by central sensitization due to activation of A beta fibres. Can be modulated by opioids, acetylcholine, substance P, NMDA antagonists, nitric oxide, and neuraxial local anesthetics

PAIN PATHWAYS IN LABOUR



Pain pathways in labor

Pain due to contraction, acute stretch and associated ischemia from the uterus travels with sympathetic fibers and enters spinal cord at T10 to L1 level. This pain is referred to anterior rami of somatic roots and upper abdominal wall anteriorly down to groin and inner aspect of thigh. Pain from peri uterine tissue from pressure either with contraction or fetal mal position or un usual conformation of sacrum travels through somatic roots of lumbo sacral plexus and this pain is located in the posterior low and mid back and also back of thigh. Pain due to distension of vagina and perineum is transmitted through somatic roots of S2, 3 and 4 nerve fibers. It is localized to the site of stimuli, not referred. Pain due to over distension of bladder travels through sympathetic fibers and reach spinal cord at T11 to L2 segments through hypogastric plexus. This pain is localized in the supra pubic region. Pain due to abruption and scar dehiscence enters spinal cord at T10 to L1 level and it is localized to the site of origin

First stage.

During the first stage pain impulse arises primarily from uterus. Stretching and distension of lower uterine segments stimulates mechano receptors. Uterine contraction may result in myometrial ischemia leading to release of bradykinin,histamine and serotonin. These noxious impulses follow the sensory nerve fibres that accompany sympathetic nerve endings; they travel through the para cervical region and hypogastric plexus to enter lumbar sympathetic chain. These stimuli enter the spinal cord at T10 to L1 segments. This pain is dull and often poorly localized

Second stage

During the second stage stretching of perineum stimulates somatic afferent nerve fibres that transmits impulses through pudendal nerve to the spinal cord at S2,3,4 levels.

Tolerance to nociceptive stimuli is increased in pregnancy due to increased plasma beta endorphin level. Neural sensitivity to local anesthetics is also increased. Progesterone has direct effect on nerve membrane excitability[4]. Analgesic effect of endogenous opioid is potentiated.

Mechanism of drug action

The proposed sites of action of local anesthetics in epidural space are

Spinal roots with in their dural root sleeves namely ink cuff zone, periphery of the spinal cord, dorsal root ganglia, and also mixed spinal nerves in the paravertebral spaces after passage outward through intervertebral foramina

Epidural test dose in labor analgesia[28]

The issue of test dose during epidural analgesia for labor pain is controversial. Even though it is routinely administered during epidural anesthesia its usefulness in labor is questionable. The heart rate variability from the pain of uterine contraction may confuse interpretation. Epinephrine containing solution may decrease uteroplacental

blood flow leading to deleterious fetal effects especially in patients with pregnancy induced hypertension and also can prolong labor.

Alternatively 1 to 2 ml of air can be injected through the catheter and listening over the precordium with external doppler can be done.

A method consist of careful injection of the local anesthetic solution in grading of 3 to 5 ml and monitoring for intravascular or sub-arachnoid injection can also be advocated. This method is employed in this study.

Complications of lumbar epidural analgesia

Hypotension is one of the common complications of epidural analgesia. High blockade or unintentional sub-arachnoid injection can cause this complication. Preloading with intravenous fluid can prevent this.

Central nervous system toxicity in the form of seizures can occur after accidental intravascular injection. Inadvertent dural puncture may cause post dural puncture headache and high blockade and total spinal. Inadequate blockade[23]- including unblocked segments and unilateral blockade can also occur. Backache is reported after epidural injection. Unrecognised uterine rupture is a potential complication.

Indications and contraindications for epidural labor analgesia

Maternal indications for epidural analgesia in labor includes maternal pain, the primary indications, maternal request, dysfunctional labor especially in primi gravida. Fetal indication include pre maturity, trial of vaginal delivery.

The major contraindications are patient refusal, non availability of anesthesiology and supportive staff, systemic or severe local sepsis, major bleeding diatheses, and increased intracranial pressure.

Advantages of epidural analgesia in labor

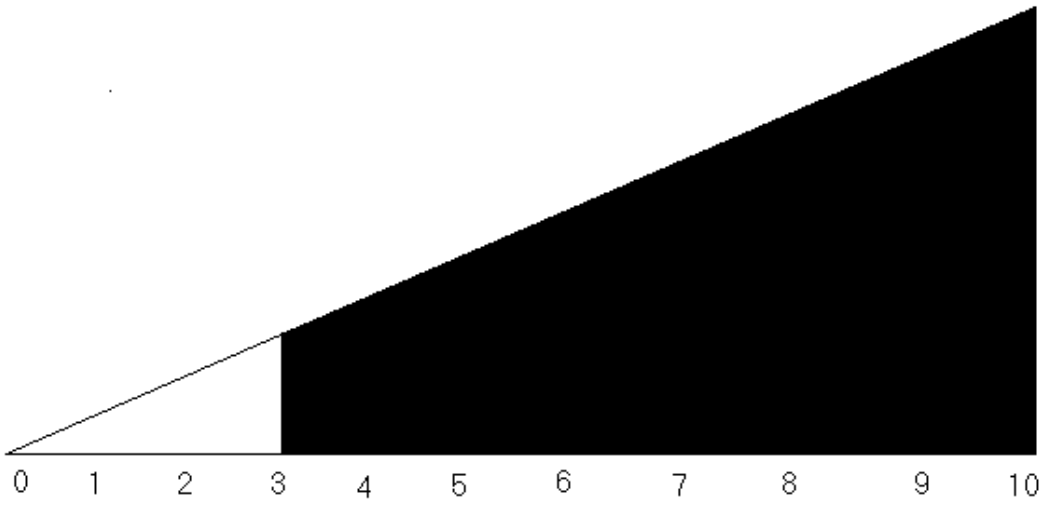
Epidural analgesia provides excellent pain relief. It increases uteroplacental blood flow by decreasing the stress of labor pain and associated increase in catecholamine release. It increases maternal oxygen saturation, which improves neonatal acid-base status. Dysfunctional labor is minimized by epidural analgesia and it allows more controlled delivery. It can be easily converted to give anesthesia for emergency caesarean section. It does not affect neonatal outcome. Consciousness of the mother is preserved hence she can actively participate in the process of labor. Epidural analgesia does not suppress airway reflexes there by decreases the chance of aspiration.

METHOD OF PAIN MEASUREMENT

Objective measurement

It is typically observational, where the investigator or clinician assigns number of grades to patients in order to scale them on one or more attributes. The criteria for scoring are well defined and independent of the patient. (NIMMO et. al., 1994)In our study we have used one such measurement namely, **visual analogue pain score chart** with numerical and descriptive scale. In this scale one end is marked as "NO PAIN" and the other end as "THE UNBEARABLE PAIN". The position of the mark on the line measures how much pain the subject experiences. If the score is less than 30 mm the pain relief is considered as good.

Visual Analogue pain score chart with numerical and descriptive scale



0 - No pain

1 - Slight Discomfort

2 - Very slight pain

3 -Light pain

4 - Light to moderate pain

5 -Moderate pain

6 – Moderate to severe pain

7 - Severe pain

8 - Very severe pain

9 - Excruciating pain

10 - Unbearable pain

METHOD OF MOTOR BLOCK ASSESSMENT

Modified Bromage scale

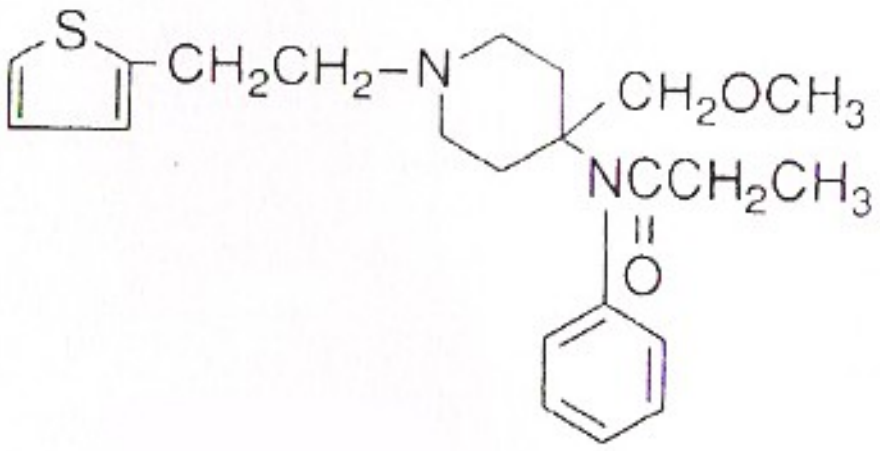
Motor blockade is assessed by Modified Bromage scale. In this scale value of less than 4 is taken as presence of motor blockade.

1. Complete blockade.
2. Able to move feet.
3. Knee flexion.
4. Weak hip flexion. Able to flex knee fully.
5. Full flexion of hip and knees.

Level of Blockade

In this study the level of sensory blockade is assessed by pin-prick test. After giving epidural injection number of segments blocked and maximum level of blockade were assessed.

DRUG PHARMACOLOGY


S
CH2CH2–N
CH2OCH3
NCCH2CH3
O

SUFENTANIL

Sufentanil is a phenylpiperidine series of synthetic opioid which is a thienyl analogue of fentanyl. The analgesic potency is 5-10 times that of fentanyl and 1000 times that of morphine. It is highly lipid soluble hence rapidly crosses blood brain barrier. It gives excellent cardiovascular system stability. Do not release histamine. Sufentanil has high hepatic extraction ratio. The first pass pulmonary uptake-60%. It is metabolized in the liver by N-dealkylation and O-demethylation. 30% is excreted in urine by conjugation. Hypothermia and advanced age prolongs elimination half life. Prolonged depression of ventilation is associated with increased plasma concentration which is seen in patients with chronic renal failure.

Pharmacokinetics

pKa	- 8.0
Percent nonionised at pH 7.4	- 20
Protein binding	- 93 (alpha 1 acid glycoprotein)
Clearance	- 900 ml/min
Volume of distribution	- 123 litres
Partition coeffeciant	- 1,727
Elimination half time	- 2.2 to 4.6 hours
Context sensitive half time	
For 4 hours infusion	- 30 minutes

Effect – site equilibration time - 6.2 minutes

Mechanism of action

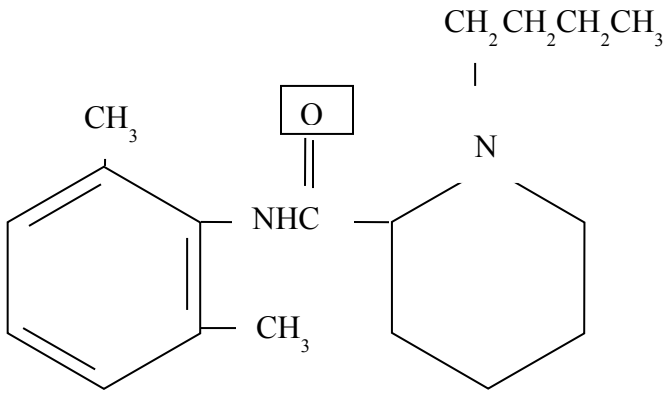
It has been well established that analgesic effects of opioids arise from their ability to inhibit the ascending transmission of nociceptive information from the spinal cord dorsal horn and also activation of pain control circuits that descend from midbrain via the rostral ventro medial medulla (RVM) to the spinal cord. In addition to spinal effects highly lipophilic opioids like sufentanil has marked systemic effects when administer through epidural route.

Opioid receptors

The major opioid receptors are Mu, kappa and Delta. The Mu receptor is further divided into Mu and Mu2. The major effects of Mu1 receptors are supraspinal and spinal analgesia, euphoria, miosis, bradycradia, hypothermia and urinary retention. Mu2 receptor causes spinal analgesia, depression of ventilation, physical dependence and constipation. The endogenous agonists for Mu receptor is endorphins. Kappa receptor produces supraspinal and spinal analgesia, dysphoria, sedation and diuresis. It has low abuse potential. The endogenous agonists for kappa receptors is dynorphin. Delta receptors produce supraspinal and spinal analgesia, depression of ventilation, physical dependence, urinary retention. The endogenous agonists is Enkephalin. The effects of opioid is reversed by antagonists namely naloxone, naltrexone and nalmefene.

Advantages of epidural sufentanil with bupivacaine[25, 26, 27]

The advantages of combining epidural sufentanil with bupivacaine are rapid onset of action when compared to bupivacaine alone. It also increases the duration of action. Concentration and dose of local anesthetic is reduced hence produces less motor blockade, hypotension, instrumental delivery, caesarean section and decreased toxic effects of local anesthetic.


CH2CH2CH2CH3
CH3
O
N
NHC
CH3

BUPIVACAINE

Bupivacaine[34,41,42] is an amide local anesthetic commonly used for spinal and epidural anesthesia and analgesia in obstetric practice. Its long duration of action, differential senrsory to motor block, and relative lack or tachyphylaxis make it a popular choice. The placental transfer of bupivacaine, as with other amide local anesthetics, is governed by two factors; the degree of ionization at physiologic pH and the extent of protein binding. Bupivacaine has limited transfer to the placenta when compared with other local anesthetics. The UV/M ratio (the ratio at delivery of the concentration of local anesthetic in blood or plasma from the umbilical vein to the concentration of local anesthetic in maternal blood) for bupivacaine ranges from 0.31 to 0.44 and is much lower than that for lignocaine. Molecular weight of bupivacaine is 288. It is first synthesized in Sweden by Ekenstam and his colleagues in 1957. Used clinically by L.J.Telivuo in 1963.

Mechanism of action

Local anesthetics produce conduction blockade of nerves. During depolarization a sudden inflow of sodium and efflux of potassium occurs. This is associated with increase in the resting membrane potential from – 70 to + 20 mV and hence action potential is generated. Local anesthetics block this sodium channels and prevent entry of sodium into the cell. As a result no action potential is generated and transmissions of

nerve impulses are blocked. Nerve fibers has two types of bundles functionally. The central fibers are called core fibers and the fibers in periphery are called mantle fibers. The core fibers supplies distal part of their area of innervations where as mantle fibers supply proximal parts. As time elapses after the injection of local anesthetic the concentration in the mantle fiber gets diminished where as in core fibers the concentration is still maintained. So analgesia starts to decrease in the proximal parts earlier than the distal parts.

Pharmacokinetics

pK_a	-	8.2
Non ionized fraction at physiological pH	-	15 %
Protein Binding	-	95 %
Lipid Solubility	-	28
Volume of distributions	-	73 litres
Clearance of the drug from plasma	-	0.47 l/mm
Distribution half life t/2 a	-	2.7 min
t/2 b	-	28 min
Eliminate half life	-	210 min
Maximum single dose for infiltration in adults	-	175 mg
Duration of action following infiltration	-	5-16 hrs
Onset of action (Epidural)	-	15-20min

Maximum dose	-	2 mg/Kg with or without adrenaline
Toxic concentration	-	> 1.6 mg/ml

Note: Addition of adrenaline to bupivacaine has no effect on its duration of action except that it delays absorption of local anesthetics due to vasoconstriction from the site of administration.

The metabolism of bupivacaine takes place in the liver by N-dealkylation, the metabolite pipecolyloxylidine is excreted in the urine. Less than 2% of the drug is excreted unchanged in urine. The rate of clearance is dependent on hepatic blood flow and drug excretion by the liver.

The advantages of epidural bupivacaine

When used epidurally for labor pain it produces high- quality analgesia. The motor blockade when used in low concentration is minimal. It has long duration of action. The umbilical vein to maternal arterial concentration ratio in about 0.32 Compared with a ratio of 0.73 for lignocaine. Although it crosses placenta, no adverse effect noted in neonates even after infusion of 0.125% bupivacaine 10 ml/hr for upto 15hrs. It produces excellent pain scores of less than 10 on a scale of 0-100. It is widely available

Toxic manifestations

The toxic manifestations of epidural bupivacaine includes hypotension, bradycradia, circurlatory failure. In central nerves systems it may cause restlessness,

circumoral numbness, light headedness, tremor, and convulsion. In the respiratory systems it may cause medullary depression, apnoea, and respiratory failure. Rarely it may produce allergic reactions.

Disadvantages of giving local anesthetic alone

When local anesthetics alone are used for epidural analgesia during labor pain, the concentration required is high. It cause more intense motor blockade leading to blockade of perineal musculature early in labor. Hence the incidence of instrumental delivery and prolonged labor is high. The cardiovascular toxicity and other adverse effects is also more. Intense sympathetic blockade leads to marked hypotension and adverse fetal effects.

Disadvantages of giving opioid alone

Opioid as single agent in epidural space is associated with inadequate pain relief, tachyphylaxis, nausea, sedation, respiratory depression, pruritus, and depressant effect on the fetus. The duration of action is unpredictable when used alone.

Advantages of combining local anesthetic with opioids

To over come this hurdle, local anesthetics and opioids are combined and administered epidurally to give pain relief. It is more advantageous than giving either of these alone. It provides adequate analgesia. The total dose requirement of both are reduced. Hence the toxic effects are also minimal. This combination produce less motor blockade, minimal sympathetic blockade, lower frequency of instrumental delivery. The neonatal outcome is not affected.

MATERIALS AND METHODS

After obtaining the approval of the local ethics committee of Thanjavur Medical College Hospital, the Study was conducted on 30 parturient in Gravida I and II and American Society of Anaesthesiologist classification I. For the purpose of standardization, selection criteria were fixed as age between 20 and 32 years, weight between 50-65 kg and height between 145 and 160cms.Informed consent was obtained from the patients after explaining the procedure in detail. All the paturients were thoroughly examined and basic data like blood pressure, heart rate, status of cardio-vascular, respiratory and neurological system were recorded.

Patients with Pregnancy Induced Hypertension, respiratory problems, cardiovascular, neurological or any other systemic disorders, Anemia, multiple pregnancies, abnormal presentation were excluded from the study.

Resuscitative measures including Boyle's apparatus with oxygen, emergency airway devices and all emergency drugs were kept ready before starting the procedure.

After securing intravenous line, all the patients were given premedication with injection. Rantidine 50mg and Metoclopromide 10mg intravenously and 500ml of Ringer lactate was infused.

Monitoring is done with NIBP, pulseoximetry and ECG .Base line blood pressure and pulse rate were recorded. At the onset of labor when the cervical dilatation is 4 to 5 centimeters as assessed by the obstetrician, patient was positioned in lateral decubitus position. Under strict aseptic precaution, after infiltration with local anaesthetic in L_2-L_3

interspace epidural space was approached through a midline approach using 17 gauge Tuohy needle. Identification of the epidural space was done with loss-of-resistance to air technique.A 19G catheter was introduced into the space and secured in place after leaving 3-5 cm inside the epidural space. 10ml of local anesthetic solution containing injection bupivacaine 0.0625% with injection sufentanil 1micro gm/ml of local anesthetic was injected slowly after careful aspiration for CSF and blood. After repositioning the patient, a wedge was placed properly to displace the gravid uterus

After initiating the procedure blood pressure was recorded for every five minutes for 30 minutes and then for every 15 minutes. Pulse rate and oxygen saturation were monitored continuously. Onset of pain relief and level of blockade were assessed using pin prick test. Pain was assessed with visual analogue pain score chart immediately before epidural injection and at five minute intervals for the first 30 minutes after bolus injection, then every hour until birth. Motor blockade was assessed using modified Bromage scale in which score of less than 4 is considered as presence of motor blockade. Duration of analgesia is defined as the period between the first painless contraction after epidural injection and the appearance of pain subsequently.

The obstetrician observes nature of uterine contractions, cervical dilatation, progress of labor and fetal heart rate

Hypotension is treated with injection Ephedrine and crystalloids when systolic blood pressure fall is greater than 30% of the baseline value or falls below 90mm Hg systolic. Bradycardia is treated with injection atropine 0.6 mg intravenously as and when

required

Additional doses consisting of 5ml of 0.0625% bupivacaine and sufentanil 1micro gm/ml of local anesthetic was given when the analgesia wears off and the patient complains of pain. During II Stage of labor if analgesia is not adequate as evidenced by patient complaining of pain another dose of 10 ml of 0.0625 bupivacaine and sufentanil 1micro gm/ml of local anesthetic is given. Similar precautions and monitoring were employed.

OBSERVATION AND RESULTS

The total number of patients in this study group is 30. Only Gravida I and II patients were selected with American Society of Anaesthesialogy classification I. The drug administered was 10ml of 0.0625% bupivacaine with sufentanil 1micro gm/ml.

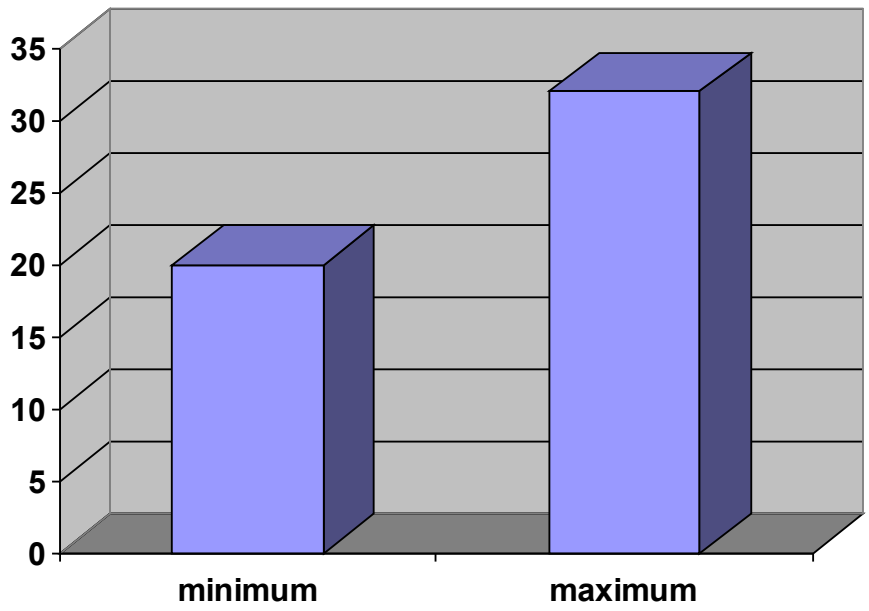
Physical characteristics

Age distribution

The minimum age in this study group is 20 years and the maximum age is 32 years. 22 patients were between 20 and 25years and 7 patients were between 26 to 30 years and 1 patient was above 30 years

Age Group	No. of Patients
20-25 years	22
26-30 years	7
30-32 years	1

Age Distribution



Weight distribution

The Weight of the patients in this study group ranges between 50 to 65kg. 24 patients were between 50 to 55kg and 6 were between 56 to 60 kg and 3 patient had weight above 60kg.

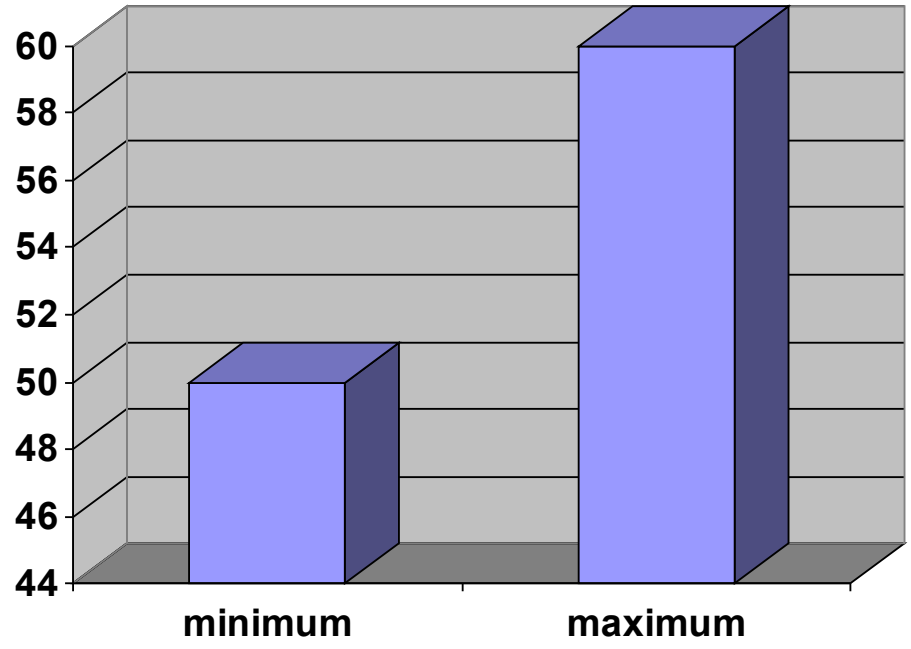
Weight Range	No. of Patients
50 – 55 kg	21
56 – 60 kg	6
61 – 65 kg	3

Height distribution

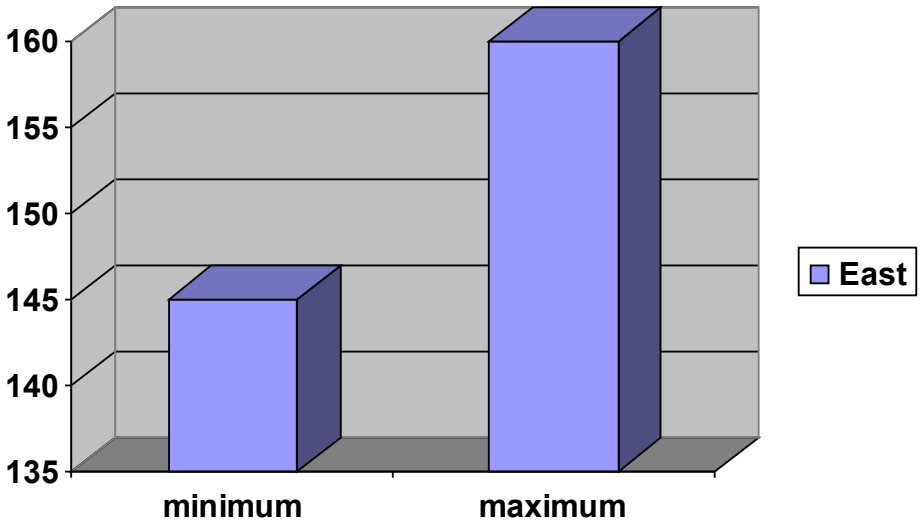
The height distribution of the parturients in this study ranges between 145 and 160 cms. 13 patients were in the range of 145 to 150 cm and 14 patient had range of 151 to 155 cm and 3 patient were in the range of 156 cm to 160 cm.

Height Range	No. of Patients
145 – 150 cm	13
151 – 155 cm	14
156 – 160 cm	3

Weight Distribution



Height Distribution



Onset of pain relief

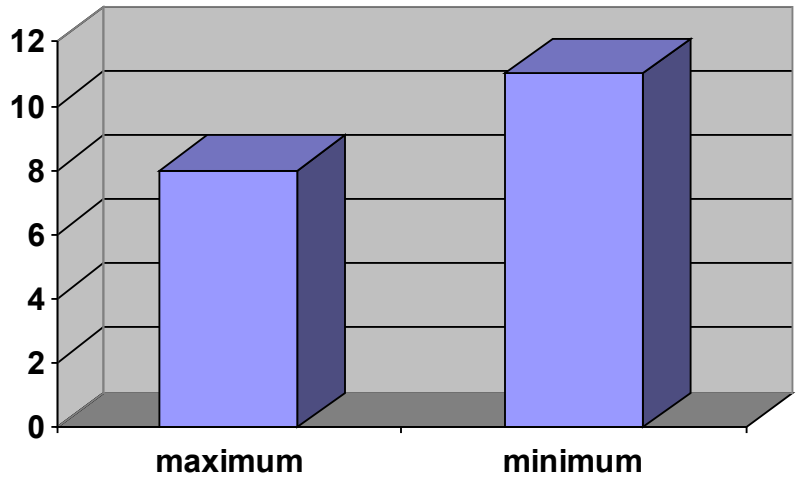
In this study the onset of analgesia ranged between 8 to 11 minutes. In 8 patients the onset time was between 8 to 9 minutes and in 16 patient the onset time was between 9 to 10 minutes and in 6 patient it is between 10 to 11 minutes.

Onset time	No. of patient	Percentage
8 – 9 min	8	26.6%
9 – 10 min	16	53.33%
10 – 11 min	6	20%

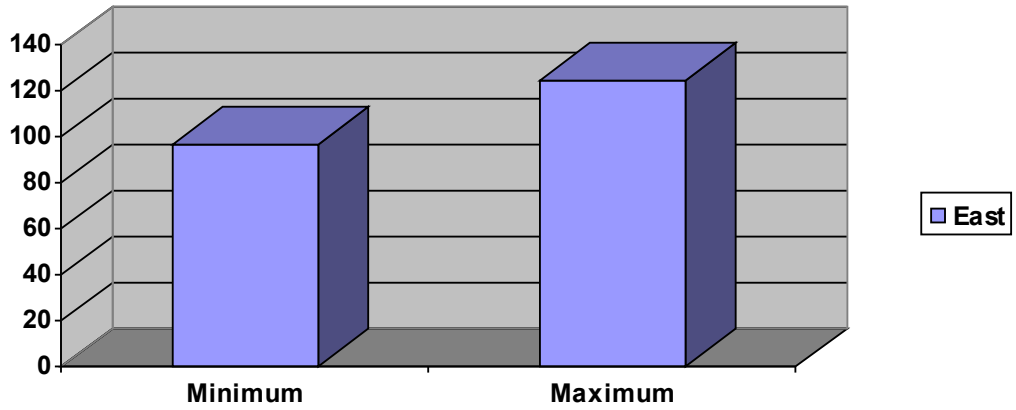
Satisfactory analgesia[31,33]

Satisfactory analgesia was reported by 94% of the parturient. It is assessed by visual analogue pain score chart with numerical and descriptive scale which showed < 30mm on the scale at 15minutes. The visual analogue score before the administration of epidural analgesia was more than 70mm. 28 patient in the study group showed a score of less than 30mm after giving epidural analgesia.

Onset Time



Duration of Analgesia



Duration of analgesia[15, 32]

In this study the duration of analgesia ranged between 96 to 124 minutes. In 12 patients the duration was between 96 to 110 minutes which is about 40% and in 18 patients the duration was between 110 to 124 minutes and this account to 60% of the total.

Level of blockade

In this study the highest level of blockade as assessed by pin prick test was T8. 2 patients had level of blockade upto T8 and in 5 patients it was upto T9. In 23 patients the level was limited to T10 level.

Motor blockade[16]

In this study group, none of the patient developed motor blockade of less than 4 according to the modified Bromage scale. All were ambulant.

Hypotension

In this study 3 patients developed fall in systolic blood pressure of less than 90mm Hg. In all the three patients, hypotension occurred after the initial bolus dose. They were treated with injection Ephedrine 6 mg intravenously and with crystalloids. The incidence of hypotension in this study is 10 %.

Neonatal outcome[17]

90% of the babies had APGAR of 9 at 1 minute. All the babies had score of 9 at 5 minutes. 1 baby showed 1 minute APGAR of 7 which is about 3.3 % and 2 babies had score of 8 at 1 minute and this comes to about 6.6%. In all the three babies, the score improved to 9 at 5 minutes.

Instrumental / Caesarean delivery

In this study the incidence of instrumental delivery occurred in one parturient which is about 3.3 %. Outlet forceps was applied. The pain during the procedure was bearable by the patient. There is no incidence of caesarean delivery in this study.

Other effects

Pruritus occurred in 4 patients in this study which is about 14 %. It is mild and none of the patients required treatment. There is no incident of vomiting and respiratory depression in any of the parturients in this study.

REVIEW
OF
LITERATURE

1. **Morgan BM, Bulpitt CJ and Clifton P** et al ; in their comparative study in the year 1992 in 1000 mothers confirmed that lumbar epidural analgesia provides superior pain relief and proved strikingly more effective than systemic medication , inhalational analgesia and pudendal block.

2. **David.H.Rosan M** studied effect of epidural analgesia and perinatal mortality in 6000 births and demonstrated less neonatal mortality, especially for low birth weight babies when mothers had epidural analgesia.

3. **Harrison and Clowers** examined depth of lumber epidural space at different inter spaces in 1000 parturient and found that it is greatest in the second lumbar inter space and ranges between 4 and 8 mm.

4. **Deckardt R, Fernbacher P.M, schneider KT**. et al: studied effect of labor pain on maternal oxygen saturation and neonatal acid base status. They concluded that primipares having effective lumber epidural analgesia showed a significantly smaller decrease in SaO_2 and better neonatal acid base status.

5. **Janbu,** in the year 1989 showed that labor pain induced vasoconstriction diminishes blood flow in dorsalis pedis an radial arteries up to 80% during contraction and this is abolished by effective epidural analgesia.

6. **Chestnut DH, Owen CL, Bates JN** et al: compared continuous infusion of 0.0625% bupivacaine. Plus fentanyl 0.0002% with 0.125% bupivacaine alone for labor analgesia and concluded that both groups had comparable analgesia but motor blockade was less in group bupivacaine 0.0625% plus fentanyl 0.0002%.

7. **Chestnut DH, Laszewski, Pollock KL** et al: studied effect of continuous infusion of 0.0625% bupivacaine + 0.0002% fentanyl even with full cervical dilatation and found no difference in duration of second stage of labor, instrumental deliveries, and neonatal outcome in this group and saline placebo group.

8. **Saunders NJ, Spiby H, Glibert L** et al: studied the effect of oxytocin infusion during second stage of labor in primipares and concluded that oxytocin achieves a reduction in non rotational forceps deliveries and perineal trauma.

9. **Abboud TK Khoo S.S. Miller F** et al: compared bupivacaine, lidocaine, and chloroprocaine for mean duration of pain relief and observed that mean duration of pain

relief with bupivacaine is 115 min.

10. **Eisenach JC, Grice SC, Dewan DM** studied the effect of adding epinephrine to bupivacaine. They concluded that addition of epinephrine enhances bupivacaine analgesia, decreases bupivacaine's latency of onset from 8.7 min to 5.8 min and also prolongs analgesia but the potential complications are decreased uterine blood flow and possible prolongation of labor.

11. **Philips** in his comparative study of sufentanil and saline added to bupivacaine for epidural analgesia for labor pain concluded that sufentanil fastens the onset time, prolongs duration of analgesia from 90 min to 144 min.

12. **Vansteenberge A, DeBroux HC** in their study of extradural bupivacaine with sufentanil for vaginal delivery, pointed out that addition of sufentanil to bupivacaine significantly shortened the onset time and prolonged the duration of action from 86 min in control group to 130 min in sufentanil group.

13. **Naulty JS, Rose R, Bergen W** in their study on epidural sufentanil- bupivacaine for analgesia during labor and delivery concluded that addition of 5 mg of sufentanil significantly potentiates bupivacaine analgesia and enables extremely low concentration of 0.0312% to be effective.

14. **Michael S. Richmond MN, Briks RJ**. in their comparative study between single hole catheters and multi holes catheter concluded that number of unsatisfactory blocks, unilateral blocks and unblocked segments increased with single hole catheters. Also single hole catheter produces more incidence of blood tap.

15. **Scott DB** in his study on test doses in extradural block warns about the most dangerous aspect of false negative test dose and describes that no single test of accidental subarachnoid or intravascular injection is 100% reliable and every dose should be considered as test dose.

16. **Phillips.G** in his comparative study of epidural analgesia in labor between bupivacaine plus sufentanil and plain bupivacaine infusion concluded that analgesia was significantly better in sufentanil group with fewer top up requirement and less motor blockade.

17. **Benhamon D, Mercier.F.J, Ben Ayed M** compared the efficiency of Bupivacaine in lower concentration of 0.0625% plus sufentanil 0.5 and Bupivacaine 0.125% alone by continuous epidural for labor pain and concluded that, more pronounced motor block occurs with bupivacaine 0.125 % group than with bupivacaine and sufentanil group. Requirement of top up doses in bupivacaine 0.125% group is high (32 Vs 8 p=0.03). The rate of assisted delivery in bupivacaine and sufentanil group is less. (92% Vs 74%

p=0.09). No difference in fetal or neonatal outcome in both groups.

18. **Boselli E, Debon R, Duflo F and Bryssine** studied the effect of sufentanil in decreasing the dose of local anesthetic when added together. They added sufentanil 0.5mg/ml with Ropivacaine 0.1% for labor pain relief and concluded that addition of sufentanil decreased the local anesthetic dose requirement by 30-40%

19. **Rolfseng Ok, Skogvoll.E, Borchgrevink Pc** compared the efficiency of epidural sufentanil and fentanyl when added with bupivacaine for labor analgesia. One group received bupivacaine 1mg/ml plus sufentanil 1micro gram/ml and another group bupivacaine 1mg/ml and fentanyl 3.5 micro gram/ml. The results showed that onset time is little early with sufentanil. Pain relief which is assessed by visual analogue scale and maternal satisfactions are equal in both groups. More importantly all parturient can stand alone and walk for 20 meters without help.

20. **Dahl V, Hagen, Koss KS, Nordentoft J, Raeder JC.** in a study with different concentration of bupivacaine and sufentanil 1 microgram/ml for labor analgesia concluded that analgesia with low dose bupivacaine (0.625 mg/ml) and sufentanil is as good an analgesic method as high dose bupivacaine (2.5mg/ml).

21. **Shinder AM, Wright RG, Levinson G**, et al, in their study in pregnant ewes

demonstrated that stress induced by labor pain increases the norepinephrine level and maternal mean arterial pressure and concomitant decrease in uterine blood flow and deletanion fetal effects.

22. **Hollmen A, Jouppila R, Jouppila P**, et al; in their study using radioactive xenon-133 demonstrated a 35% increase in intervillous blood flow in healthy laboring parturient after epidural analgesia with 0.25% bupivacaine or 2% 2-chloroprocaine.
23. **Bromage PR**: In the 1960s studied the requirement of local anesthetic in term pertinent and found that it is about a third less than that of the non pregnant women.
24. **Bonica JJ** narrated that once labor is established; epidural analgesia can actually accelerate labor in patients who had previously demonstrated a dysfunctional labor pattern.
25. **Leighton BD, Norris MC, Sosis M**, et al; in their study concluded that usefulness of an epinephrine containing test dose is controversial in the laboring patient since pain induced tachycardia may confuse the interpretation of increased heart rate response seen with intravascular injection. Systemic absorption of epinephrine may decrease uterine blood flow and can cause deleterious effect on fetus.

DISCUSSION

Pain experienced by the parturient during the process of vaginal delivery is one among the severe form of pain. Knowing this, measures were taken since the period of Grantly Dick-Read and then by Dr. Fernand Lamaze. Later, various methods were developed. Among these, epidural analgesia for labor pain relief remains the most effective method. **Morgan BM** and his colleagues in their comparative study of 1000 mothers confirmed that lumbar epidural analgesia provides superior pain relief and proved strikingly more effective than other modalities of pain relief. Studies analyzing the effects of labor on maternal and fetal physiology depicts that the unfavorable effects of labor pain are minimized by proper administration of epidural analgesia

Stress and pain induced release of catecholamine during labor causes decreased uteroplacental blood flow leading to deleterious fetal effects. Studies using xenon-133 clearance shows that epidural analgesia increases intervillous blood flow. Maternal oxygenation is also improved by epidural analgesia as shown by **Deckardt** in his study. Neonatel mortality is decreased especially in low birth weight babies when mothers had epidural analgesis as shown by **David .H. Rosen** in his study.

In this study, epidural injection of combination of 10 ml of 0.0625% bupivacaine and sufentanil 1 micro gram per ml in relieving labor pain is proved effective and beneficial. **Phillips. G.** in his comparative study found that addition of sufentanil to bupivacaine significantly improves analgesia than using bupivacaine alone.

Adding sufentanil also decreases the requirement of local anesthetic, enables them to be used in low concentrations and decreases the side effects.

Boselli E. and his colleagues in their study on labor analgesia concluded that Sufentanil decreases the local anesthetic dose requirement by 30 to 40%. **Naulty JS** also showed that addition of even 5 micro gram of sufentanil to bupivacaine significantly potentates analgesia and enables extremely low concentration of 0.0312% to be effective.

In this study the minimum time taken for onset of pain relief is 8 min and the maximum is 11 minutes with mean of 9.5 minutes.

Rolfseng in his comparative study of epidural sufentanil and fentanyl with bupivacaine concluded that the mean onset time for sufentanil is 10 min. It is in concurrence with our study.

Satisfactory analgesia is reported by 94% of parturients in this study. It is assessed by visual analogue pain score chart with numerical and descriptive scale. It showed less than 30mm at 15minutes after administration of epidural analgesia.

Dahl V In his study of labor analgesia with combination of bupivacaine and sufentanil showed that 97% of the mothers had satisfactory analgesia. **Rolfseng** also showed similar results in his study. Both are in concurrence with our study.

Duration of analgesia in this study ranges between 96 minutes and 124 minutes with mean duration of 110 minutes. Studies show that addition of sufentanil to bupivacaine increases the duration of action of bupivacaine and also shortens the onset

time.

Vansteenberg and DE Broux in a study pointed out that addition of sufentanil to bupivacaine shortened the onset time and prolonged the duration of action from 86 minutes in control group to 130 minutes in sufentanil group.

Phillips in his comparative study concluded that sufentanil when added to bupivacaine prolongs duration of analgesia from 90 minutes to 144 minutes.

In this study motor blockade had not occurred in any patient. It is assessed by modified Bromage scale. According to this scale motor blockade is defined as scale of less than 4. In this study group all the parturient can flex their hip and knees and all are ambulant.

Benhamon in his comparative study of 0.0625% and 0.125% bupivacaine with sufentanil 0.5 micro gram /ml concluded that 0.0625% bupivacaine produce less motor blockade. **Rolfseng** in his comparative study using bupivacaine and sufentanil for labor analgesia showed that all parturient can walk for 20 meters with out help.

There is only one incidence of instrumental delivery in this study. Studies show that epidural analgesia when instituted properly decreases the incidence of instrumental deliveries and dysfunctional labor. There is no incidence of caesarean delivery.

Benhamoh D in a comparative study showed that combination of bupivacaine and sufentanil decreases the rate of assisted delivery.

In our study three patients had fall in blood pressure of less than 90 mm Hg

systolic. All were treated with Injection Ephedrine and crystalloids. In all the three patients it occurred with the initial dose. In all other parturient the hemodynamics were stable.

H.J. Clement and his colleagues in a comparative study of bupivacaine and ropivacaine with sufentanil showed that incidence of hypotension was 10%. It is in concurrence with our study.

In this study 4 parturient had pruritus, which is about 14%. It is tolerable by the patients. Studies show that the range of incidence for pruritus is wide.

Dahl.V.and his colleagues in their study of epidural analgesia for labor with bupivacaine and sufentanil had 18% incidence of pruritus. But **H.J. Clement** and his colleagues in their comparative study came across with incidence of 45% for pruritus.

Neonatal outcome is not affected in this study. One minute APGAR is 7 in only one baby and 8 in two babies. It improved to 9 at five minutes score in all the three babies. All the others had score of 9.

Deckardt. R. and **Fembacher** in a study showed that epidural analgesia actually improves neonatal outcome by maintaining the neonatal acid- base status by virtue of increasing maternal oxygen saturation.

CONCLUSION

This study proves that the combination of 0.0625% bupivacaine and sufentanil 1 micro gram/ml of local anesthetic is effective in relieving labor pain. The motor blockade is very minimal which makes the parturient ambulant. There is no increased incidence of complications and assisted or caesarean deliveries. The neonatal outcome is good.

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PROFORMA

Case No……

Name of the patient :

Unit :

Age :

I.P.No :

Height :

Date of Admission :

Weight :

Date of Study :

Educational Status :

EXAMINATION OF THE PATEINT

General :

CVS :

BP :

RS :

PR :

CNS :

Preloading :

Position of the Patient : Right/ Left Lateral / Sitting

Technique : Midline/ Para median

Time of Drug injection :
(Based on cervical Dilatation)

Onset of Pain Relief :

Level of sensory Blockade :

Degree of Motor Blockade : **I** **II** **III** **IV**
(Modified Bromage Scale)

Duration of Motor Blockade:

Quality of Analgesia :

Duration of Analgesia :

Systolic BP														
Diastotic BP														
Pulse rate														
Ephedrine														
Fetal Heart rate														

Labor Natural :

Episiotomy pain :- Yes/No

Instrumental Delivery : Outlet Forceps / Vaccum Delivery / Caesarean Section

APGAR Score :

Maternal Satisfaction :

COMPLICATIONS

Urinary Retention :

Maternal Bradycardia :

Pruritus :

Respiratory Depression :

Nausea /Vomiting :

Drowsiness / Sedation :

Rigors :

Others :

Signature of HOD

MASTER CHART

S. No.	Name of the Patient	IP No.	Age in Years	Height in Cms	Weight in Kgs	Cervical Dilatation in cm	Amount of Sufentanil (Micro Gm)	A B
1	Mrs.Maheswari	1867	21	150	60	4	30	
2	Mrs.Kolambal	2637	28	155	55	5	20	
3	Mrs.Poongodi	2622	20	152	52	5	20	
4	Mrs.Shanmugapriya	2889	25	150	50	5	20	
5	Mrs.Malathy	3091	24	148	50	5	20	
6	Mrs.Suseela	3212	28	150	62	5	30	
7	Mrs.Dhanalakshmi	3181	20	148	50	4	30	
8	Mrs.Vijayalakshmi	3354	29	154	56	5	20	
9	Mrs.Magamayi	3452	25	156	58	5	20	
10	Mrs.Selinmary	3649	32	155	60	5	20	
11	Mrs.Badha	3745	22	153	55	5	20	
12	Mrs.Selvi	3905	28	149	50	5	20	
13	Mrs.Santhana Lakshmi	4158	27	151	64	5	20	
14	Mrs.Jayanthi	4194	22	154	55	5	20	
15	Mrs.Venilla	4297	24	148	50	5	20	
16	Mrs.Devaki	4463	22	153	52	5	20	
17	Mrs.Papathy	4472	22	150	50	5	20	
18	Mrs.Selvi	4671	25	157	60	5	20	
19	Mrs.Banu	4757	25	155	65	5	30	
20	Mrs.Prabavathy	4558	26	151	52	5	20	
21	Mrs.Gomathy	4984	25	148	50	5	20	
22	Mrs.Anjammal	2799	20	150	52	4	30	

23	Mrs.Parvathy	5191	30	154	54	5	20	
24	Mrs.Kavitha	5525	24	147	50	5	20	
25	Mrs.Mahalakshmi	5592	22	156	55	5	20	
26	Mrs.Parimala	5507	20	150	50	5	20	
27	Mrs.Usha	5751	20	154	54	4	30	
28	Mrs.Chitra	5957	25	155	52	5	20	
29	Mrs.Priya	6065	25	150	55	5	20	
30	Mrs.Chitra	6214	22	155	57	5	20	